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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicant	:	Klenk et al.
App. No	:	10/783,783
Filed	:	February 20, 2004
For	:	DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE WITH A COIL-SHAPED CLOSURE DEVICE
Examiner	:	Diane D. Yabut
Art Unit	:	3734

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**Mail Stop AF**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Applicant respectfully requests review of the final rejection set forth in the Final Office Action ("Office Action") dated November 20, 2009 in the above-identified application. Applicant's claims have been twice rejected, and as such Applicant may appeal the Examiner's decision to the Board of Patent Appeals and Interferences. No amendments are being filed with this request. Enclosed with this Request is a Notice of Appeal.

**REASONS FOR REQUEST**

The Office Action maintains the rejection of Claims 1-15, 17-25 and 28-32 under 35 U.S.C. § 103(a) as unpatentable over Chanduszko (U.S. Publ. 2005/0059984) in view of Johnson (US 6,485,504). Claims 27 and 33-35 are rejected under 35 U.S.C. § 103(a) as unpatentable over Chanduszko in view of Johnson in further view of Kay (U.S. 5,662,683). The Examiner's rejections contain clear errors of fact in the combination of the Chanduszko and Johnson references and omit essential elements needed for a prima facie obviousness rejection. The Examiner's errors are indisputable and not subject to interpretation, and therefore, must be reversed.

**The Examiner's Combination of Chanduszko with Johnson Contains Clear Errors of Fact and Omits Essential Elements Needed For A Prima Facie Obviousness Rejection**

The Examiner's rejection of all of the pending claims attempts to combine the coil disclosed in Johnson with the tissue piercing structure disclosed in Chanduszko. In Applicant's Response of July 27, 2009 ("Applicant's Response") at pages 9 to 12, Applicant argued that the proposed combination would render Chanduszko inoperable because placing the coil 100 of Johnson on the outside of the elongate member 104 of Chanduszko would make it impossible for the coil to function with Chanduszko's delivery member 106 disposed inside the elongate member 104. In the Response to Arguments at page 5 of the Office Action, the Examiner states "the modification [of Chanduszko with Johnson] is *not* meant to alter the position of Chanduszko's releasably engageable proximal end 142 of anchor 108 to a loading portion 106, which is disposed inside of the elongate member 104 (Figures 12A-12D)." (emphasis added).

However, at page 4 this is the modification the Examiner suggests: "It would have been obvious to one of ordinary skill in the art at the time of invention to modify Chanduszko et al. by having coil anchors with a distal end of the coil being releasably engaged to the distal end of the elongate body, as taught by Johnson et al., in order to effectively narrow the coil in diameter to facilitate deployment and also to minimize damage to tissue and allow flexibility and movement by the patient without disturbing the healing process." Office Action at 4. Specifically, and as further explained in Applicant's Response at page 12, Johnson teaches a coil "grommet" 100 placed on the outside of a pushing rod 108 and releasably engaged with an opening 116. The grommet taught in Johnson narrows about the outside of the pushing rod 108, and relies on contact between the proximal end of the grommet and the hard bone surface to cause the grommet to axially elongate and radially reduce. Thus, the use of the grommet as taught by Johnson is incompatible with the system of Chanduszko, which places its suturing device *inside* the elongate member 104.

In the Office Action at page 6, the Examiner now appears to be proposing a different modification to Chanduszko involving "modifying the I-shaped anchor 108 [of Chanduszko] into a coil anchor with a distal end that would be coupled to a slot in the distal end of elongate member 104 instead of having a free distal end, as taught by Johnson." However, this modification clearly misapplies the teachings of Johnson. Nowhere does Johnson teach connecting its grommet to a slot at a distal end of an elongate member, where the grommet is

located inside the elongate member. In fact, such a modification would be inconsistent with the Examiner's stated purpose for the modification, i.e., "in order to effectively narrow the coil in diameter to facilitate deployment through tissue and also to minimize damage to tissue and allow flexibility and movement with the coil anchor without disturbing the healing process." Office Action at 4. Placing the coil of Johnson inside the elongate member 104 of Chanduszeko has no effect on the ability of the coil to be passed through tissue, because the coil would remain inside the elongate member 104 that is passed through tissue. Further, the Examiner states: "To have both ends of an anchor be releasably engaged to the delivery device rather than just one suggests a more controlled positioning and release of the anchor within tissue, as taught by Johnson." Office Action at 6. However, because the coil of Johnson would be located within the elongate member of Chanduszeko, there would be no way to release the anchor into tissue until the distal end of the coil is released from the elongate member.

In addition, the Examiner's proposed combination of Chanduszeko with Johnson omits essential elements needed to make an obviousness rejection. Because the proposed combination fails to accomplish the stated purpose articulated by the Examiner, one skilled in the art would have no reason to make the combination with any reasonable expectation of success. Moreover, the Examiner offers no explanation for how the coil would be released from *inside* the elongate member, with both the proximal end and distal end coupled inside the elongate member. For example, Claim 1 recites "wherein the coil when released contracts to pinch the septum primum and the septum secundum together." Therefore, the Office Action fails to explain how one of skill in the art would make the asserted combination to produce the claimed invention with any reasonable expectation of success. As further explained in Applicant's Response at pages 7 to 9 (reiterating the requirements set forth in the PTO's Examination Guidelines for an Examiner to make an obviousness rejection), the Examiner's obviousness rejections are based merely on conclusory statements, and fail to include specific findings of fact concerning the level of ordinary skill in the pertinent art, the specific rationales for the proposed combination, and explicit explanations of the modifications necessary to make the proposed combination. Accordingly, Applicant submits that the Examiner's obviousness rejections are improper.

**The Proposed Combination of Chanduszko with Johnson To Teach The Use Of A Plurality of Coils Omits Essential Elements Needed For A Prima Facie Obviousness Rejection**

In contrast to the combination of Chanduszko and Johnson, Applicant's Claim 12 recites, in part, "releasably engaging a plurality of discrete implantable coils with a single delivery device, the single delivery device comprising a tissue piercing structure, the plurality of discrete implantable coils comprising a distal most coil releasably engaging the tissue piercing structure and one or more proximal coils positioned axially along the single delivery device." The Office Action has failed to explain *why* one skilled in the art would have found it obvious to use a plurality of coils, and has not provided any evidence supporting the obviousness finding, either in another reference or based on the knowledge or common sense of one having ordinary skill in the art.<sup>1</sup> In light of the prior art limiting itself to the use of a single coil, it would not have been obvious to use a plurality of coils to close a PFO.

The Office Action at p. 4 states: "[i]t would have been obvious to one of ordinary skill in the art to modify the loading portion of Chanduszko et al. to accommodate multiple anchors or coils in order to further secure the septum primum and septum secundum together." In the Response to Arguments at page 6, the Examiner offers little more than repeating this conclusory statement, adding that "the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." However, nowhere has the Examiner (1) identified the knowledge one skilled in the art would possess, (2) described what modifications the skilled person would need to make to combine the prior art references, or (3) discussed whether that skilled person would have a reasonable expectation of success. Accordingly, Applicant again re-submits that the Examiner's obviousness rejections are improper.

Claim 12 also recites "retracting the tissue piercing structure proximally to engage an additional coil without removing the tissue piercing structure from the body of the patient." Again, the Office Action's cited combination does not suggest how, upon retracting the tissue piercing structure, an additional coil would be engaged with the tissue piercing structure without removing the tissue piercing structure from the body of the patient. Accordingly, Applicant submits that Claim 12 is allowable over the combination of Chanduszko in view of Johnson.

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<sup>1</sup> 72 Fed. Reg. at 57528 ("The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.").

**The Office Action Contains Clear Errors With Respect to Claims 33-35**

With respect to the Examiner's rejections over Chanduszko in view of Johnson and Kay, Applicant has already explained why the combination of Chanduszko with Johnson is improper, and has not addressed in detail the impropriety of the combination with Kay. In Applicant's Response at pages 17 to 18, Applicant further explained that Claims 33-35 recite a loading collar provided "over the tissue piercing structure." Nowhere does the Examiner address this claim limitation in the Office Action. Moreover, nowhere is this feature found in Chanduszko, Johnson or Kay. Accordingly, Applicant submits that the Office Action omits essential elements needed to establish a prima facie rejection of Claims 33-35.

**Dependent Claims**

Claims 2-11 depend from Claim 1, Claims 13-19 depend from Claim 12, Claims 21-25 and 27-30 depend from Claim 20, and Claims 32-35 depend from Claim 31, are believed to be patentable for the same reasons articulated in Applicant's July 27, 2009 Response with respect to the independent claims, and because of the additional unique features recited therein. Accordingly, it is respectfully submitted that Chanduszko, Johnson and Kay, alone or in combination, do not teach or suggest all the limitations of these claims or the independent claim from which these claims depend, and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.

**Conclusion**

In view of the foregoing, Applicants respectfully submit that the obviousness rejections of the pending claims are improper and the pending claims are in condition for allowance. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Monday, March 01, 2010

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